REMARKS

The Official Communication dated July 28, 2004 concerned Applicant's May 3, 2004 reply to a non-final Office Action dated December 30, 2003. The July 28, 2004 Communication stated that Applicant's May 3, 2004 reply to the December 30, 2003 Office Action was non-responsive for failure to include a reply to each and every ground of rejection and objection set forth in the December 30, 2003 Action, namely, addressing the outstanding rejections under 35 U.S.C. §112, first paragraph for written description and enablement, under 35 U.S.C. §112, second paragraph, and under 35 U.S.C. §101. This paper is being filed to supply the responsive statements deemed to be missing from Applicant's May 3, 2004 Reply.

Status of the prosecution:

Claims 1-8 and 12-13 were examined, and the following rejections were set forth in the December 30, 2003 Office Action: (1) claims 1-3, 5 and 12-13 were rejected under 35 U.S.C. §112, first paragraph, for alleged lack of adequate written description; (2) claims 1-8 and 12-13 were rejected under 35 U.S.C. §112, first paragraph, for alleged lack of enablement by the specification; (3) claim 1, and claims dependent therefrom were rejected under 35 U.S.C. §112, second paragraph, for alleged indefiniteness in the recitation of "functions in meiotic cells of plants to maintain normal pairing of homologous chromosomes;" and (4) claims 1-8 and 12-13 were rejected under 35 U.S.C. §101 for alleged lack of utility, and under 35 U.S.C. §112, first paragraph for alleged lack of enablement on the same ground.

In Applicant's May 3, 2004 Reply to the December 30, 2003 Office Action, claims 1-8 and 12-13 were cancelled, and new claims 27-36 were added. New claims 27-36 were discussed with the examiner in a telephonic conference and have been revised in accordance with the examiner's suggestions as discussed in the teleconference. New claim 27 is directed to an isolated nucleic acid molecule having a sequence greater than 95% identical to SEQ ID NO:1, and encoding a polypeptide that contains a cyclin structural domain and functions to maintain normal pairing of homologous chromosomes during meiotic prophase I. New claim 34 is directed to an isolated nucleic acid molecule comprising SEQ ID NO:1.

Applicant respectfully submits that the claims as amended are in condition for allowance, for the reasons set forth below.

The written description requirement of 35 U.S.C §112, first paragraph, is satisfied:

Claims 1-3, 5 and 12-13 stand rejected under 35 U.S.C. §112, first paragraph, for alleged lack of adequate written description in the specification. The rejection is premised on the ground that the application does not describe a representative number of isolated nucleic acid molecules of the genus that have the recited structural features and a specific function associated with those features. Applicant submits that the rejection should not be applied to the presently pending claims. Independent claim 27 is directed to isolated nucleic acid molecule comprising a nucleotide sequence greater than 95% identical to SEQ ID NO:1, said nucleic acid molecule encoding a polypeptide that contains a cyclin domain, wherein the polypeptide functions to maintain normal pairing of homologous chromosomes during meiotic prophase I in meiotic cells of plants. The instant specification describes one representative member of this genus (SEQ ID NO:1) having the recited function. The structural scope of the genus is small – sequences with greater than 95% homology to SEQ ID NO:1. Accordingly, Applicant submits that the claimed genus is adequately supported by a single representative species, wherein the specific function is recited as a limitation of the claim. Accordingly, the rejection for lack of written description should not be applied to claims 27-33.

Claim 34 is directed to an isolated nucleic acid molecule comprising SEQ ID NO:1. This claim is comparable to canceled claim 8, which was not rejected for lack of adequate written description. Accordingly that rejection should not be applied to claims 34-36.

For the foregoing reasons, the currently pending claims should be found to satisfy the written description requirement of 35 U.S.C. §112, first paragraph, and the rejection should be withdrawn.

The enablement requirement of 35 U.S.C §112, first paragraph, is satisfied:

Claims 1-8 and 12-13 stand rejected under 35 U.S.C. §112, first paragraph, for alleged lack of enablement by the specification. The Action alleges that undue experimentation would be required to use the claimed invention. The Action acknowledges that the instant specification discloses empirical evidence of a loss of protein function *in situ* by insertional disruption of the protein coding region of SEQ ID NO:1 that results in gross and fine phenotypic changes. However, the Action asserts that the specification provides no guidance with respect to how to use an isolated nucleic acid molecule of SEQ ID NO:1 to achieve the same phenotypic effect; therefore it would require undue experimentation for one of skill in the art to determine how to use SEQ ID NO:1 or homologs thereof.

Applicant submits that the rejection should not be applied to the presently pending claims. The claims are directed to isolated nucleic acid molecules having SEQ ID NO:1 and their very close homologs (greater than 95% identity), encoding a cyclin domain-containing polypeptide. The specification clearly teaches that insertional disruption within the coding region of this nucleic acid results in several phenotypic changes that lead to abnormal pollen formation (specification, page 9, lines 13-20; Example 1). The specification further teaches how to use SEQ ID NO:1 or its close homologs to make a transgenic plant that has a similar loss of the SEQ ID NO:1 gene product as does the null mutant described in the specification. For example, the specification at page 19, line 21 through page 20, line 20, teaches:

> A synthetic null mutant can be created by a expressing a mutant form of the SDS protein to create a "dominant negative effect". While not limiting the invention to any one mechanism, this mutant SDS protein will compete with wild-type SDS protein for interacting proteins in a transgenic plant. By over-producing the mutant form of the protein, the signaling pathway used by the wild-type SDS protein can be effectively blocked. Examples of this type of "dominant negative" effect are well known for both insect and vertebrate systems (Radke et al, 1997, Genetics 145:163-171; Kolch et al., 1991, Nature 349:426-428).
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> A second kind of synthetic null mutant can be created by inhibiting the translation of the SDS mRNA by "post-transcriptional gene silencing". The SDS gene from the species targeted for down-regulation, or a fragment thereof, may be utilized to control the production of the encoded protein. Full-length antisense molecules or antisense oligonucleotides are used that are targeted to specific regions of the SDS-encoded RNA that are critical for translation. The use of

> antisense molecules to decrease expression levels of a pre-determined gene is known in the art. Antisense molecules may be provided in situ by transforming plant cells with a DNA construct which, upon transcription, produces the antisense RNA sequences. Such constructs can be designed to produce full-length or partial antisense sequences. This gene silencing effect can be enhanced by transgenically over-producing both sense and antisense RNA of the gene coding sequence so that a high amount of dsRNA is produced (for example see Waterhouse et al., 1998, PNAS 95:13959-13964). In a preferred embodiment, part or all of the SDS coding sequence antisense strand is expressed by a transgene. In a particularly preferred embodiment, hybridizing sense and antisense strands of part or all of the SDS coding sequence are transgenically expressed.
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> A third type of synthetic null mutant can also be created by the technique of "co-suppression". Plant cells are transformed with a copy of the endogenous gene targeted for repression. In many cases, this results in the complete repression of the native gene as well as the transgene. In a preferred embodiment, the SDS gene from the plant species of interest is isolated and used to transform cells of that same species.

Citing research papers from as long ago as 1988 and 1990, the examiner asserts that the art of disrupting gene expression in plants is unpredictable; therefore undue experimentation would be required in order to use the nucleic acid molecules of the invention for such purposes. Applicant disagrees. Such methods have been commonly used for many years since 1990 by biologists in all fields. Accordingly, while some experimentation may be required to identify the best means by which to disrupt gene expression, the methods are *currently* sufficiently commonplace that the experimentation would be of a routine nature. The test of enablement is not simply whether experimentation would have been necessary, but whether such experimentation would have been undue. See *In re Angstadt*, 190 U.S.P.Q. 214, 219 (C.C.P.A. 1976). The fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation. See *In re Wands*, 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1988). In the art of plant physiology, genetics and molecular biology, the experimentation described above is typical, and therefore is not undue. Accordingly, withdrawal of the rejection is requested.

The definiteness requirement of 35 U.S.C §112, second paragraph, is satisfied:

Claim 1, and claims dependent therefrom were rejected under 35 U.S.C. §112, second paragraph, for alleged indefiniteness in the recitation of "functions in meiotic cells of plants to maintain normal pairing of homologous chromosomes." Applicant submits that this rejection should not be applied to the currently pending claims. Claim 27 now recites an isolated nucleic acid molecule that encodes a cyclin-containing polypeptide that functions to maintain normal pairing of homologous chromosomes during meiotic prophase I in meiotic cells of plants. The specification teaches, and it is known in the art, that cyclins are regulatory proteins. The specification further teaches several specific phenotypic features associated with loss of function of the protein, which further delineates the function of the protein. Thus, the recitation of function in claim 27, combined with the teachings in the specification and the knowledge of the skilled artisan, would clearly inform one of the skill in the art as to the metes and bounds of the claimed invention. Accordingly, withdrawal of the rejection is respectfully requested.

The utility/enablement requirements of 35 U.S.C. §§101/112 ¶ 1 are satisfied:

Claims 1-8 and 12-13 stand rejected under 35 U.S.C. §101 for alleged lack of utility, and under 35 U.S.C. §112, first paragraph for alleged lack of enablement on the same ground. Applicant submits that the rejection should not be applied to the presently pending claims. The Action alleges that the function of the product of SEQ ID NO: 1 or its close homologs has not been established "empirically or by specific correlation." Applicant disagrees. As discussed above, the specification establishes empirically that disruption of the protein coding region of SEQ ID NO:1 results in abnormal pollen formation, which has a specific and substantial utility in male sterility. Then, as discussed above, the specification further teaches how to use SEQ ID NO:1 to create transgenic plants wherein the endogenous gene expression is disrupted. Though the specification provides no working examples of such transgenic plants, the teachings are undeniably present in the specification, and the relevant art is sufficiently well developed that the skilled artisan would recognize the asserted utility of SEQ ID NO:1 and its close homologs for this purpose as a credible utility. For these reasons, Applicant asserts that

the claimed invention has utility within the meaning of 35 U.S.C. §101, and further that one of skill in the art would know how to use the invention, in satisfaction of the requirements of 35 U.S.C. §112, first paragraph. Accordingly, withdrawal of the rejections is requested.

Conclusion:

In view of the amendments submitted in Applicant's May 3, 2004 Reply, and the foregoing remarks, the presently-pending claims are believed to be in condition for allowance. Applicant respectfully requests early and favorable reconsideration and withdrawal of the rejections set forth in the December 30, 2003 Action, and allowance of this application.

Respectfully submitted,

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